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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,807	12/16/2003	Jay Miazga	000309-00261	2864
27557	7590	05/26/2006	EXAMINER	
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			SMITH, STEPHANIE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/735,807

Applicant(s)

MIAZGA ET AL.

Examiner

Stephanie Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 10, drawn to a percutaneous coupling apparatus comprising an electrode and coupling member, classified in class 607, subclass 115.
- II. Claims 11-12, drawn to a percutaneous coupling and control system, classified in class 607, subclass 2.
- III. Claims 13-16, drawn to a method for operating a percutaneous coupling apparatus, classified in class 607, subclass 142.
- IV. Claim 17, drawn to a method for operating a percutaneous apparatus, classified in class 607, subclass 149.
- V. Claims 8, 9, and 18-27 drawn to a percutaneous housing apparatus, classified in class 607, subclass 150.
- VI. Claims 28-31, drawn to a method applying a percutaneous apparatus to the skin, classified in class 607, subclass 145.
- VII. Claims 32-42, drawn to a percutaneous attachment apparatus, classified in class 607, subclass 46.
- VIII. Claims 43-44, drawn to a dual percutaneous apparatus, classified in class 607, subclass 48.
- IX. Claims 45-46, drawn to a percutaneous conductive link apparatus, classified in class 607, subclass 63.

Art Unit: 3762

- X. Claims 47-48, drawn to a percutaneous spine method, classified in class 607, subclass 43.
- XI. Claims 49, 52, and 53, drawn to a percutaneous housing and attaching to the skin method, classified in class 607, subclass 142.
- XII. Claims 50-51, drawn to a method for operating two percutaneous devices, classified in class 607, subclass 62.

Inventions III, IV, VI, X-XII (process) and I, II, V, VII-IX (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice another and materially different process not requiring percutaneous (through the skin) use of the probe but using the probe for testing the internal temperature of non-living objects, such as a hydrogel or food.

Inventions XII (combination) and III, IV, VI, X, and XI (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a coupler, forcing two segments toward each other, stowing the probe, deploying two probes, a flexible support surface, or aligning the housing with the skin. The subcombination has

Art Unit: 3762

separate utility such as not requiring a control unit or selecting one of two probes, but a capacitor and resistor to deliver a pulse or selecting both probes.

Inventions X (combination) and III, IV, VI, and XI (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a coupler, forcing two segments toward each other, stowing the probe, a flexible support surface, or aligning the housing with the skin. The subcombination has separate utility such as not requiring deploying two probes, but deploying only one probe.

Inventions XI (combination) and III, IV, and VI (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a coupler, forcing two segments toward each other, or stowing the probe. The subcombination has separate utility such as not requiring releasably attaching the housing to the skin surface or orienting the skin surface to match a contour of the skin or flexing the support surface, but using a fixed shaped housing and orienting it in any direction on the skin.

Inventions IV (combination) and III and VI (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require contacting first and second sections of the electrode with a conductive portion of the aperture or moving the probe at a selected angle such as 90 degrees. The subcombination has separate utility such as not requiring forcing segments toward each other, but just inserting the probe without forcing segments together.

Inventions VI and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a coupler with an aperture. The subcombination has separate utility such as not requiring stowing the probe, but inserting the probe before use and discarding the probe separately after use.

Art Unit: 3762

Inventions IX (combination) and I, II, V, VII, and VIII (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require being returned to a neutral position, having a 180 degree bend, the control unit transmitting and receiving, having a support surface that is not contoured but has a different irregular shape, and a second probe. The subcombination has separate utility such as not requiring a control unit or an electrically conductive link releasably coupled between the control unit and probe, but just a capacitor and resistor to apply a pulse or the conductive link fixed between the control unit and probe.

Inventions II (combination) and I, V, VII, and VIII (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require being returned to a neutral position, having a 180 degree bend, a housing, an attachment device, and a second probe. The subcombination has separate utility such as not requiring a control unit to transmit and receive, but to only transmit or no control unit and just a capacitor and resistor to apply a pulse.

Inventions VII (combination) and I, V, and VIII (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination does not require being returned to a neutral position, having a 180 degree bend, a coupling member having an aperture, the angular orientation of the probe in the housing, the transverse direction in the housing, or that the probe be coupled to a control unit to control transmitted signals. The subcombination has separate utility such as not requiring an attachment device depending from the housing or just a capacitor and resistor to apply a pulse, but using the housing to steady the probe on the patient, and a control unit to transmit.

Inventions VIII (combination) and I, V (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require being returned to a neutral position, having a 180 degree bend, the first end being in the housing when in a stowed position, the angular orientation of the probe in the housing, the transverse direction in the housing, or an attachment device. The subcombination has separate utility such as not requiring two probes but only one probe.

Inventions V and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a coupling member having an aperture. The subcombination has separate utility such as not requiring a housing, but used solely with a probe and coupling member.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Michael Greenbaum on May 22, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 3762

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRS

GEORGE R. EVANISKO  
PRIMARY EXAMINER  
5/25/6